

REMARKS

The foregoing amendment is submitted to more particularly set forth the claimed invention and to emphasize the distinguishing features over the prior art. In this regard, Applicants wish to thank Examiners Corbin and Lytle for the courtesies extended in the personal interview on August 6, 2004. During the interview, it was stated that Applicant will overcome the section 112 rejection and discuss how the primary reference (Bell et al.) does not meet the minimum daily calcium requirement in the manner performed by the present invention.

The present invention is directed to a centerfilled chewing gum composition comprising a shell portion and a centerfill portion. An object of the present invention is to provide a meaningful amount of a calcium-containing compound in the centerfill portion.

The present invention provides a sufficient amount of available calcium so that the user of the chewing gum product can obtain at least the minimum daily nutritional requirements of calcium during the course of a day while chewing a reasonable number of pieces of gum.

There have been prior art efforts to place calcium in a chewing gum composition and in the centerfill portion thereof. There are several considerations in addressing a deliverable form of calcium in a chewing gum composition. First, calcium-containing compounds can range from essentially water soluble materials

such as calcium citrate to essentially sparingly water soluble or non-water soluble materials such as calcium carbonate. If water soluble calcium compounds were capable of delivering a sufficient amount of calcium to the user so as to meet the minimum daily nutritional requirements during the course of a day while chewing a reasonable number of pieces of gum, then the delivery of calcium in a chewing gum composition would be a relatively simple task. However, water soluble calcium-containing compounds do not possess a sufficiently high calcium content to readily provide an effective amount of calcium through a chewing gum composition. Accordingly, it is desirable to include sparingly soluble or non-water soluble calcium compounds for the delivery of calcium through a chewing gum composition.

Another factor which affects the delivery of calcium through a chewing gum composition is the amount of the calcium-containing compound which is actually released from the chewing gum composition during a normal chewing cycle. If the calcium-containing compound is bound up in the chewing gum composition and is not released during the normal chewing cycle, then the available calcium for delivery to the oral cavity will be insufficient and will not likely meet the minimum daily requirements of most individuals.

Use of non-water soluble and sparingly soluble calcium-containing compounds, while advantageous over water-soluble calcium-containing compounds, nonetheless, present significant problems. These compounds have a high affinity for

ARK:jsg090104/1901033.AMD

the gum base and therefore become trapped therein so that in typical chewing compositions, much of the calcium is not available for delivery to the oral cavity.

To overcome this problem, calcium-containing compounds have been placed in a centerfill chewing gum composition so that the calcium compounds are not placed in proximity to the gum base and therefore do not become entrapped therein. However, the placement of calcium-containing compounds in the centerfill of a chewing gum composition still does not provide effective release of the calcium so that an effective amount of calcium may be provided to the oral cavity to meet the minimum daily nutritional requirements of calcium for the user chewing a reasonable number of pieces of gum per day.

Applicants have discovered that it is necessary to ensure that the calcium-containing compound is effectively suspended and dispersed throughout the centerfill portion in order to provide effective delivery of the calcium in a centerfill chewing gum composition. This provides a relatively high solids content and therefore high delivery of the calcium without adversely affecting the viscosity of the centerfill to a point where the taste and/or sensory characteristics of the chewing gum composition are compromised. Applicants have therefore discovered that it is necessary to suspend and relatively uniformly disperse the calcium-containing compound within the centerfill portion.

It is important to note that chewing gum compositions can be an effective vehicle for delivering active agents but are limited in that the active agent must be

ARK:jsg090104/1901033.AMD

provided in a minimum effective amount in the oral cavity by chewing no more than a reasonable number of pieces of gum per day. Quite obviously, if the minimum amount of the active agent could only be provided by chewing thirty pieces of gum per day, the chewing gum composition would not be viable for delivery of the active agent. A reasonable number of pieces of chewing gum per day can vary among individuals. As indicated on page 5, line 27 of the present application, a reasonable number of pieces can be regarded as three to five pieces per day for most individuals.

In order to suspend the calcium-containing compound within the centerfill portion and to provide relatively uniform distribution, Applicants have discovered that this can be accomplished, for example, by employing a preselected particle size for the calcium-containing compound and/or by employing an effective amount of a suspending agent.

The average particle size of the calcium compound is typically less than about 17 microns (see original claim 7). Alternatively or in conjunction with the selection of the particular particle size is the employment of a suspending agent (see original claims 2 and 3).

The prior art cited in the Office Action does not teach or suggest the need to suspend the calcium-containing compound within the centerfill to obtain a uniform distribution which enables the delivery of the calcium-containing compound in a chewing gum composition to the user in a manner which provides the minimum daily

ARK:jsg090104/1901033.AMD

nutritional requirement of calcium through the use of no more than a reasonable number of pieces of the chewing gum composition.

The claims of the application have been amended consistent with the comments made herein. Claim 1 has been amended to indicate that the centerfill portion comprises at least one calcium-containing compound which is suspended in the centerfill portion. The calcium is relatively uniformly dispersed in the centerfill portion without settling and is present in an effective amount sufficient to provide at least the minimum daily nutritional amount of calcium to a user by chewing a reasonable number of pieces of the chewing gum composition per day. Support for claim 1 can be found in the paragraph bridging pages 6 and 7 of the specification which discusses effective suspension and dispersion of the calcium within the centerfill portion. The requirement of a sufficient amount of calcium to meet the daily nutritional requirements through a reasonable number of pieces of gum is set forth on page 5, lines 13-22. It is therefore submitted that claim 1 as amended does not raise a new matter issue and entry thereof is deemed proper and is respectfully requested. The amendment of claim 1 has necessitated the cancellation of claim 17.

As previously indicated, another way of achieving the objects of the present invention is by employing a suspending agent. This aspect of the claimed invention is now set forth in claim 2 as well as new claim 19 and is supported on page 8, lines 15-20. New claims 20-23 correspond to original claims 3-6 and new claims 24-33

ARK:jsg090104/1901033.AMD

essentially correspond to the subject matter of original claims 8-16 and 18. It is therefore submitted that new claims 19-33 are fully supported in the application as filed.

Referring to the Office Action, original claims 1-18 stand rejected under 35 U.S.C. Section 112 on the ground that the phrase "effective amount" does not explain the function of the effective amount of the calcium compound. This rejection is deemed overcome in light of the amendments to the claims which now provide that the amount of the calcium compound must be sufficient to provide at least the minimum daily nutritional amount of calcium to a user by the chewing of a reasonable number of pieces of chewing gum per day. Withdrawal of the rejection is therefore deemed proper and is respectfully requested.

All of the claims of the application have been rejected as anticipated by or obvious over Bell et al. (WO 00/06127), alone or in combination with secondary references as discussed below. Reconsideration of the present application in light of the amendment and the following discussion is respectfully requested.

Bell et al. discloses a centerfill chewing gum composition which includes a hard outer shell and a soft center fill. The purpose of the reference invention is to provide a delivery system for nutraceuticals which can include mineral salts such as calcium compounds (page 9, line 32, page 10, line 3). The active agents can be incorporated into the hard shell, the centerfill or both.

Bell et al. represents the state of the art prior to the present invention. In particular, it was known from Bell et al. that the centerfill could be used to incorporate active agents including calcium compounds. However, there is no teaching or suggestion in Bell et al. of the problems associated with providing enough available calcium so that a chewing gum can be used as a delivery system for delivering an effective amount of a calcium-containing compound to the oral cavity to achieve the minimum nutritional dose requirements to a user from a reasonable number of pieces of gum per day. This is the research and development which led to the present invention.

There is no teaching or suggestion in Bell et al. of the problem associated with delivering an effective amount of calcium and how to solve the problem. In particular, Bell et al. does not teach or suggest that a calcium-containing compound must be suspended and relatively uniformly dispersed within the centerfill portion of the chewing gum composition. Furthermore, there is no teaching or suggestion of the employment of a suspending agent and/or a particular particle size for the calcium compound in order to suspend the calcium-containing compound within the center fill and to provide for a uniform distribution of the calcium within the entire center fill.

One of ordinary skill in the art based on Bell et al. would have to rely on undue experimentation in order to achieve the present invention because there is no teaching or suggestion of how to solve the problem of delivering the requisite amount

ARK:jsg090104/1901033.AMD

of calcium to the oral cavity. It is therefore submitted that Bell et al. alone does not teach or suggest the invention as now claimed in the present application.

Claim 3 stands rejected as obvious over the combination of Bell et al. in view of Friello et al. or Glass. The Office Action states that it would have been obvious to use pectin, alginate or CMC as the hydrocolloid in Bell et al. since anyone of these hydrocolloids is conventionally included in the centerfill portion of the chewing gum which also contains glycerin as evidenced by Friello et al. The rejection is hereby traversed and reconsideration is respectfully requested.

Friello et al. discloses at column 1, lines 33-39 the employment of a centerfill containing from about 94 to about 99.5% by weight of a glycerin dispersion containing from about 0.5 to about 6% by weight of a thickening agent which as the Examiner correctly notes can include carboxymethyl cellulose, pectin, alginates and the like. The purpose of the glycerin is to provide a sweetening affect to the chewing gum composition and the thickening agent is intended to prevent an increase in viscosity of the glycerin. While it is noted that the centerfill can contain optional and minor amounts of a sweetener, sugar, and sugar alcohol, there is no teaching or suggestion of employing the centerfill for delivery of a calcium-containing compound. The combination of Bell et al. and Friello et al. does not lead one of ordinary skill in the art to the present invention. This is because Friello et al. requires that virtually the entire centerfill be filled with glycerin and a thickening agent. There

ARK:jsg090104/1901033.AMD

is no teaching or suggestion of the employment of an active agent and certainly no suggestion of the addition of a calcium-containing compound for delivering an effective amount of calcium to the oral cavity.

In addition, there is no teaching or suggestion in the reference of how to modify the Bell et al. reference in order to achieve a calcium-containing compound in the centerfill which is suspended therein and which is uniformly distributed therein. Even if it could be argued that the two references could be combined, there is no teaching or suggestion by the combination of references that one could achieve a centerfill chewing gum containing a calcium-containing compound suspended therein which is uniformly distributed within the centerfill portion. At best, the combination of references is an invitation to experiment and can only arrive at the presently claimed invention by the improper use of hindsight reconstruction.

Claims 10 and 12 stand rejected over the combination of Bell et al. and Cherukuri. The Office Action states that it would have been obvious to include calcium carbonate as a filler-texturizing agent in the centerfill core of Bell et al. since it is conventional to include calcium carbonate in the soft core portion of a chewing gum which has an outer shell. The rejection is hereby traversed and reconsideration is respectfully requested.

The filler-texturizing agent disclosed in Cherukuri as exemplified by calcium carbonate is employed to adjust the texture of the gum to impart good lubricant and flavor release properties. However, Cherukuri does not cure the deficiencies of the

ARK:jsg090104/1901033.AMD

primary reference. There is no teaching of uniformly suspending a calcium containing compound in the centerfill such as by adding a suspending agent and/or restricting the particle size of the calcium-containing compound in order to provide a centerfill having a deliverable amount of a calcium-containing compound which can be delivered to the oral cavity of the user with the use of a reasonable number of pieces of gum per day.

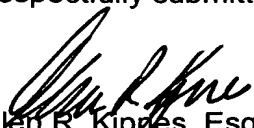
As previously indicated, Bell et al. does not teach or suggest the importance of suspending the calcium-containing compound in the centerfill portion of the chewing gum. Cherukuri merely provides that calcium carbonate can be used as a texturizing agent in the centerfill portion but there is no teaching or disclosure of how to deliver an effective amount of calcium to the oral cavity nor any means for doing so. Accordingly, the combination of Bell et al. and Cherukuri does not lead one of ordinary skill in the art to the claimed invention.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

ARK:jsg090104/1901033.AMD

Applicants enclose herewith a check in the amount of \$198.00 to cover the fee for additional claims. If any additional fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,



Allen R. Kipnes, Esquire
Registration No. 28,433
Attorney for Applicant

Address All Correspondence to:
Allen R. Kipnes, Esquire
WATOV & KIPNES, P.C.
P.O. Box 247
Princeton Junction, NJ 08550
(609) 243-0330